DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

Our STN: BL 103770/5022

OCT 23 2002

Peter Patriarca, M.D.
Medimmune, Incorporated
25 West Watkins Mill Road
Gaithersburg, MD 10878

Dear Dr. Patriarca:

Your request to supplement your biologics license application for Palivizumab to revise the Warnings and Adverse Reactions sections to include anaphylaxis and to revise the Immunogenicity subsection has been approved.

We acknowledge your written commitment of October 23, 2002, to send a Dear Healthcare Professional letter that communicates the updated information to the package insert. You will submit the first draft within one week with a target completion date of two weeks, not to exceed one month.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

This information will be included in your biologics license application file.

Sincerely yours,

Karen D Weiss

Karen D. Weiss, M.D.
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Division of Clinical Trial
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